K130231

Section 5 510(k) Summary

(As required by 21 CFR 807.92(a))

5.1 Submitter Information

- Company: Jinxinbao Electronic Co., Ltd
- Address: No.38, Huanzhenxi Road, Dagang Town, Nansha, Guangzhou, China
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- Email: xhoucc@jxb-htb.net
- Contact: Jiacheng Guo, General Manager

- Date: November 25, 2012

5.2 Device Information

- Trade/Proprietary Name: Non-contact Infrared Thermometer-JXB 182
- Common Name: Infrared Thermometer
- Classification Information: Classification: 2

  Review Panel: General Hospital

  Name: Thermometer, Electronic, Clinical

  Regulation Number: 21 CFR 880.2910

  Product Code: FLL

- Predicate Device: Remote Infrared Thermometer, Model RC002, K090361
- Device Description:

All objects, solid, liquid or gas, emit energy by radiation. The intensity of this energy depends on the temperature of the object. The JXB-182 infrared thermometer is therefore able to measure the temperature of a person by the energy the person emits. This measurement can be taken thanks to an external temperature probe on the device which permanently analyses and registers the ambient temperature. Therefore, as soon as the operator holds the thermometer near the forehead and activates the radiation sensor, the measurement is taken instantly by detection of the infrared heat generated by the arterial blood flow. Body heat can therefore be measured without any interference

from the heat of the surrounding environment.

The JXB-182 thermometer without contact has been developed using latest infrared technology .This technology allows temporal artery (TA) temperature to be taken at a distance of about 5cm away from the forehead. Then the result will be displayed on LCD. Besides, it owns Led backlight which can show three different colors in different temperature ranges and three-language prompt function.

• Intended Use:

JXB-182 Non-contact Infrared Thermometer is an infrared thermometer intended to measure forehead temperature of infants and adults without contacting human body. It can be used by consumers in household environment and doctor in clinic as reference.

5.3 Comparison of Required Technology Characteristics

Item	Subject Device	Predicate Device
Device Name	Non-contact Infrared Thermometer Model JXB-182	Remote Infrared Thermometer Model RC002
Measurement Method	Infrared Radiation Detection	Infrared Radiation Detection
Range	**In body mode:** 32~42.9° C	**In body mode:** 32~42.9° C
Accuracy	± 0.3℃	± 0.3℃
Precision	± 0.3℃(34-35.9° C) ± 0.2℃(36-39° C) ± 0.3℃(39-42.5° C)	± 0.3℃(34-35.9° C) ± 0.2℃(36-39° C) ± 0.3℃(39-42.5° C)
Measurement Distance	3cm~5cm	5cm~8cm
Power Supply	DC 3V (2AA Batteries)	DC 3V (2AA Batteries)
Material	ABS	ABS
Operating Condition	Temperature: 10° C to 40° C Humidity rate: ≤ 95%	Temperature: 10° C to 40° C Humidity rate: ≤ 85%
Display	LCD	LCD
Display Resolution	0.1° C	0.1° C

Dimension	175×50×52mm(L×W×H)	196×150×50mm(L×W×H)
Weight	148g	220g
With Led Backlight	Yes, with three colors	Yes
Automatic Stop	5 seconds	5 seconds
Language Prompt Function	Yes, three languages (French, English, Spanish)	No

Brief Summary:

The subject device – JXB 182 Non-contact Infrared Thermometer enjoys almost the same design and technological characteristics with the predicate device, such as the same measurement method, accuracy, precision, power supply, display, material and measurement range, and the similar operating condition and measurement distance.

Though they differ in dimension and weight, such trivial difference in appearance will not affect the core function of the device, let alone affecting the comparison of substantial equivalence. Also they are different in Led backlight and language prompt function, that is, the subject device has two more functions – three-color backlight and three-language prompt function than the predicate device. But such addition will not affect their core usage of the device. Besides, the tests mentioned below have demonstrated the subject device is as safe and effective as the predicate device.

5.4 Discussion of Tests Performed

Clinical Tests:

Subject device JXB 182 is compliant to the ASTM E 1965-98(Reapproved 2009), Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature. All the relevant activities were performed by designate individual(s) and the results demonstrated that the predetermined acceptance criteria were fully met.

Non-clinical Tests:

The subject device was tested to evaluate its safety and effectiveness according to the following applicable standards:

· **Electrical Safety:**

IEC 60601-1 Medical electrical equipment Part 1: General requirement for basic safety and essential performance

· **Electromagnetic Compatibility:**

IEC 60601-1-2: 2007 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

· **Performance Effectiveness:**

ASTM E 1965-98(Reapproved 2009), Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature.

5.5 Conclusion

The subject device, JXB-182 Non-contact Infrared Thermometer has the same intended use and similar characteristics with the predicate device. Besides, the safety of the subject has been demonstrated by the following standards: IEC 60601-1(Electrical Safety), IEC 60601-1-2(Electromagnetic Compatibility). And since the subject is composed of the same material as the predicate device, they enjoy the same biocompatibility. Moreover, the subject device meets the specific requirements of ASTM E 1965, which further embodies that the subject device is both safe and effective.

So from the above information, it is reasonable to conclude that the subject device, JXB-182 Non-contact Infrared Thermometer, is substantially equivalent to the predicate device, RC002 Remote Infrared Thermometer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 15, 2013

Jinxinbao Electronic Company, Limited
C/O Ms. Helen Nan, General Manager
Wenzhous Cytech Information Service Company, Limited
Room 404, Building 7, Jinhuichang Homeland, Liuhongqiao Road
WENZHOUS CITY, 325000, Zhejiang Province
CHINA

Re: K130231
Trade/Device Name: JXB182 Non-contact Infrared Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: II
Product Code: FLL
Dated: November 25, 2012
Received: August 7, 2013

Dear Ms. Nan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 Indications for Use Statement

510(k) Number (if known): K130231

Device Name: JXB182 Non-contact Infrared Thermometer

Indications for Use:

JXB182 Non-contact Infrared Thermometer is an infrared thermometer intended to measure forehead temperature of infants and adults without contacting human body. It can be used by consumers in household environment and doctor in clinic as reference.

Prescription Use _____ AND/OR Over-The-Counter Use ____×___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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